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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
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US/403,803 03/17/75 ISRAELI R 41426-A-PCT-

EXAMINER
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HM12/0218

JOHN P. WHITE  
COOPER & DUNHAM  
1185 AVENUE OF THE AMERICAS  
NEW YORK NY 10036

CLASSIFICATION	PAPER NUMBER
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1645

DATE MAILED: 02/18/99

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 11/16/98

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 90-99 is/are pending in the application.
- ☐ Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 90-99 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☐ Notice of Reference Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

**Part III DETAILED ACTION**

*Response to Amendment*

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Any objections or rejections made in a previous Office Action that are not herein reinstated have been withdrawn.

3. Claims 90-99 are rejected under 35 U.S.C. 112, first paragraph, for reasons of record and the following. Applicants' arguments filed 11/16/98 have been fully considered but they are not deemed to be persuasive because Applicant merely asserts that it is a routine experiment to design an appropriate probe according to the Sambrook textbook chapter provided by Applicant.

Applicant has not provided any evidence or sound scientific reasoning to overcome the grounds of the rejection due to unpredictability and undue experimentation set forth in Paper No. 14, filed 5/12/98, which deal with the PSM antigen probe in particular and specific detail. In addition, it is noted that Applicant is not limiting the claims to a probe to a known nucleotide sequence, but to a known amino acid sequence which can be encoded by a great variety of nucleotide sequences.

4. Claims 90-99 are rejected under 35 U.S.C. 112, second paragraph, for reasons of record and the following. Applicants' arguments filed 11/16/98 have been fully considered but they are not deemed to be persuasive because Applicant merely asserts that one skilled in the art would

know to use the hybridization conditions set forth in a laboratory manual such as the Sambrook textbook chapter provided by Applicant. Applicant has not provided any evidence or sound scientific reasoning to overcome the grounds of the rejection because "specifically hybridizing" conditions, as set forth in laboratory manuals, vary with the length and nucleotide composition of a particular nucleotide sequence. The instant claims do not set forth a fixed length or nucleotide composition of the probe/primer/molecule.

5. Claims 90, 92, 93, 95 are rejected under 35 U.S.C. 102(b) as being anticipated by Solin for reasons of record and the following. Applicants' arguments filed 11/16/98 have been fully considered but they are not deemed to be persuasive because Applicant argues limitations that are not in the claims. The composition of Solin contains isolated nucleic acid that could hybridize under some specific conditions meeting the limitations of the claims. The instant claims use open language so they are not limited to a single isolated nucleic acid molecule sequence. Limitations on hybridization conditions are also not recited in the instant claims, nor is degree of purity or isolation.

6. Claims 90-95 are rejected under 35 U.S.C. 102(b) as being anticipated by Faber for reasons of record and the following. Applicants' arguments filed 11/16/98 have been fully considered but they are not deemed to be persuasive because Applicant argues limitations that are not in the claims. The composition of Faber contains isolated nucleic acid that could hybridize under some specific conditions meeting the limitations of the claims. The instant claims use open language so they are not limited to a single isolated nucleic acid molecule sequence. Limitations

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on hybridization conditions are also not recited in the instant claims, nor is degree of purity or isolation.

7. No claim is allowed.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Gucker whose telephone number is (703) 308-6571. The examiner can normally be reached on Monday to Thursday from 0730 to 1800. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D., can be reached on (703) 308-3995. The fax phone number for this Group is currently (703) 308-4242, but Applicant should confirm this by phoning the Examiner before faxing.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

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Stephen Gucker

February 16, 1999



ANTHONY G. CAPUTA  
PRIMARY EXAMINER